

**916. Adulteration of Isopropyl Alcohol Compound. U. S. v. 40 Dozen and 80 Dozen Bottles of Isopropyl Alcohol Compound. Decrees of condemnation. Product ordered sold to be used for industrial purposes. (F. D. C. Nos. 7471, 7498. Sample Nos. 77124-E, 77201-E.)**

Examination showed that this product was contaminated with filth in the form of rodent hairs, human hairs, insect larvae, metal fragments, dust, and miscellaneous dirt. Inspection of the factory premises revealed the existence of very filthy conditions.

On May 6 and 13, 1942, the United States attorney for the Eastern District of Pennsylvania filed libels against 120 dozen bottles of Isopropyl Alcohol Compound at Philadelphia, Pa., alleging that the article had been shipped on or about March 5 and April 20, 1942, from Brooklyn, N. Y., by the Spark'l Co.; and charging that it was adulterated in that it was contaminated with filth, and in that it had been prepared and packed under insanitary conditions whereby it might have become contaminated with filth. The article was labeled in part: "Athlete's Isopropyl Alcohol Compound."

On April 2, 1943, no claimant having appeared, judgments of condemnation were entered and the product was ordered destroyed. On June 7, 1943, amended decrees were entered ordering the product to be sold on condition that it be used only for industrial purposes.

### DRUGS ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS<sup>3</sup>

**917. Adulteration and misbranding of digitalis tablets, misbranding of cascara compound tablets, alleged adulteration of cascara compound tablets, and alleged adulteration and misbranding of posterior pituitary solution. U. S. v. Buffalo Pharmacal Co., Inc., and Joseph H. Dotterweich. Counts charging adulteration of cascara compound tablets and adulteration and misbranding of posterior pituitary solution nolle prossed. Pleas of not guilty. Tried to the court and jury. Verdict of guilty as to the individual defendant; disagreement as to the corporate defendant. Fine, \$500 on each of 3 counts against individual defendant; payment of fines on counts 2 and 3 suspended and the individual defendant placed on probation. Judgment reversed on appeal to the Circuit Court of Appeals. Petition for Writ of Certiorari granted and decision rendered by Supreme Court reversing the judgment of the Circuit Court of Appeals. (F. D. C. Nos. 951, 2087. Sample Nos. 78710-D, 78786-D, 78814-D.)**

On April 29 and August 5, 1940, the United States attorney for the Western District of New York filed informations against the Buffalo Pharmacal Co., Inc., and Joseph H. Dotterweich, secretary and general manager of the corporation, alleging shipment on or about October 2, 1939, and January 8, 1940, from the State of New York into the States of Pennsylvania and Ohio of a quantity of digitalis tablets which were adulterated and misbranded, a quantity of cascara compound tablets which were misbranded and were alleged to be adulterated, and a quantity of posterior pituitary solution which was alleged to be adulterated and misbranded.

The digitalis tablets were alleged to be adulterated in that their strength differed from and their purity or quality fell below that which they purported or were represented to possess since each tablet was represented to possess a potency of one U. S. P. digitalis unit, whereas each tablet possessed a potency of not more than 0.48 U. S. P. digitalis unit per tablet. They were alleged to be misbranded in that the statement, "Tablets Digitalis 1½ Grs \* \* \* One USP Unit Represents (0.1 gram equals 1.543 grains) Powdered Digitalis," borne on the label attached to the bottle containing the article, were false and misleading in that the statements represented that each tablet possessed a potency of 1 U. S. P. digitalis unit, whereas each tablet did not possess such potency.

The cascara compound tablets were alleged to be misbranded in that the statement, "Tablets Cascara Compound \* \* \* (Hinkle)," borne on the bottle label, was false and misleading since it purported and represented that the article consisted of tablets of compound cascara (Hinkle), a drug the name of which, i. e., "Compound Pills of Cascara" and "Hinkle's Pills" is recognized in the National Formulary, whereas it did not consist of tablets of compound cascara (Hinkle) since it contained strychnine sulfate, an ingredient which is not included in the formula set forth as the standard for compound pills of cascara (Hinkle's Pills) in the National Formulary, official at the time of the investiga-

<sup>3</sup> See also Nos. 902, 908, 910, 914.

tion of the article. The Tablets Cascara Compound were also alleged to be adulterated on the ground that their strength and quality differed from the standard set forth in the National Formulary for Compressed Pills of Cascara, and Hinkle's Pills.

Adulteration and misbranding was also charged against a shipment of "Posterior Pituitary Solution" on the ground that its potency exceeded by 50 percent the potency of the product recognized under that name in the National Formulary.

On March 11, 1941, the defendants were arraigned and pleas of not guilty were entered on their behalf. On March 15, 1941, the defendants filed motions to quash the informations on the grounds (1) that, with respect to the digitalis tablets and posterior pituitary solution, alleged guaranties that the products complied with the law had been received by the defendant company from the vendors, and that the products had been repacked and sold without change in strength and quality; (2) with respect to the cascara compound tablets that they were labeled "Tablets Cascara Compound No. 2 S. C. Pink, (Hinkle)," and were a different product than that recognized in the National Formulary under the name of "Compound Pills of Cascara" and "Hinkle's Pills" and that there is a distinction between pills and tablets; and (3) that the individual defendant was in no way involved in any alleged adulteration and misbranding as charged since his name did not appear in the labeling of the products.

On May 8, 1941, after arguments of counsel, the motions to quash were denied by the court on the basis that objections to the informations were matters of defense which should be brought up at the trial. Subsequently, on motion of the United States attorney, the counts charging adulteration of the cascara compound tablets and adulteration and misbranding of the posterior pituitary solution were nolle prossed. The two informations were consolidated for trial before a jury on June 30, 1941, on which date the trial commenced. The taking of testimony was concluded on July 2, 1941, the jury was charged and retired and, after deliberation, returned, on the same day, a verdict of guilty on all counts as to the individual defendant, and reported a disagreement as to the corporate defendant. The individual defendant appeared for sentence on September 8, 1941, and at that time presented an argument in support of a motion to set aside the verdict. Sentence was thereupon deferred for the purpose of considering the merits of the motion and on October 17, 1941, the following opinion in denial of the motion was handed down by Hon. Harold P. Burke, United States District Judge:

BURKE, *District Judge*: "The defendant, Joseph H. Dotterweich, moves to set aside the verdict of the jury upon the ground that it was against the law and against the weight of the evidence, that the verdict as to the defendant Dotterweich was inconsistent with the disagreement of the jury in regard to the corporate defendant and therefore an illegal verdict, and that the failure of the Government to prove notice to the defendant Dotterweich of an intended prosecution under the Food, Drug and Cosmetic Act, June 25, 1938, c. 675, 52 Stat. 1040 was a condition precedent to the commencement of a proceeding against him, without which there could be no valid proceeding.

"There was sufficient evidence upon which the jury could base a verdict of guilty. The verdict was not inconsistent with the jury's treatment of the corporate defendant as to which it reached no verdict. Notice pursuant to Section 335, Title 21, U. S. C. A. of a contemplated criminal proceeding was given to the corporate defendant. Dotterweich was the General Manager and had actual notice of the contemplated proceeding against the corporation. There is nothing in the statute limiting prosecutions to those cases that have been reported by the Secretary to the United States Attorney. Prosecution for violation of the statute arising independently of any report by the Secretary would require no preliminary notice. The absence of such a limitation indicates that the requirement for notice under Section 335 should be construed as an administrative provision imposing a duty upon the Secretary. The reasoning adopted by the Supreme Court in *United States vs. Morgan*, 222 U. S. 274, in construing a provision for preliminary notice under the former statute, Section 4, Pure Food and Drug Act of June 30, 1906, 34 Stat. L. 768 C. 3915, applies with equal force to the notice required under the present statute. It was there held that the requirement for notice was not jurisdictional. I think the same reasoning impels a like conclusion here.

"Motion denied."

On October 27, 1941, the individual defendant was sentenced to pay a fine of \$500 on count 1 of the consolidated information. Fines of \$500 were also imposed on such defendant with respect to the other 2 counts of the information, but payment thereof was suspended and the defendant was placed on probation for 60 days. The case was thereafter appealed to the United States Circuit Court of Appeals for the Second Circuit, and on December 3, 1942, the following decision was handed down reversing the judgment of the District Court:

SWAN, *Circuit Judge*: "The appellant was prosecuted, together with Buffalo Pharmacal Company, Inc., a New York corporation of which he was general manager, for violations of section 301 (a) of the Federal Food, Drug and Cosmetic Act, 21 U. S. C. A. S331 (a). Three counts of the informations were submitted to the jury. The first count was based on an interstate shipment on October 2, 1939 of a bottle of cascara compound which was charged to be misbranded, 21 U. S. C. A. S352 (a); the other two counts related to an interstate shipment on January 9, 1940 of a bottle of digitalis tablets, one of the counts charging adulteration, 21 U. S. C. A. 351 (c), and the other misbranding, 21 U. S. C. A. S352 (a). Each of the shipments was made in filling an order received through the mails by Buffalo Pharmacal Company from a physician resident in a state other than New York. The corporation had purchased the drugs from a wholesale manufacturer; it repackaged them for the shipments under attack. The appellant Dotterweich had no personal connection with either shipment, but he was in general charge of the corporation's business and had given general instructions to its employees to fill orders received from physicians. The jury found guilty on all three counts. For some unexplainable reason it disagreed as to the corporation's guilt. The sentence imposed on the appellant was a fine of \$500 on each count, with payment suspended on the second and third counts, and probation for 60 days on each count to run concurrently.

"The bottle of cascara compound carried a label reading '1000 Tablets Cascara Compound \* \* \* (Hinkle),' followed by a list of the ingredients, one of which was strychnine sulphate. The charge of misbranding was based on the fact that this ingredient had been removed from the formula for Hinkle pills stated in the official National Formulary 'promulgated January 1, 1939. The issue left to the jury was whether the label was false and misleading in that it would lead the purchaser or the general public to believe that the tablets contained only the ingredients designated in the official formula for Hinkle pills. Since intention to violate the statute is immaterial in a charge of misbranding,<sup>4</sup> we think the jury's finding that the label was false and misleading was not unsupported by the evidence.

"The label on the bottle of digitalis tablets represented that each tablet possessed a potency of one U. S. P. unit of digitalis, whereas in fact analysis proved that the tablets were less than one-half of the represented potency. This was so far below the standard that findings of adulteration and misbranding would seem to be inevitable, unless the deterioration occurred after the bottle of tablets was shipped. It was shipped on January 9, 1940 and its contents were analyzed by government chemists in March 1940. While cross examination brought out that digitalis tablets may deteriorate in potency by lapse of time if not properly stored, there was some testimony to indicate that the bottle in question had been properly cared for. We cannot say that the evidence was insufficient to support the verdict of adulteration and misbranding."

"Section 305 of the Act, set forth in the margin,<sup>5</sup> provides that before the Administrator reports a violation to any United States attorney for prosecution, 'the person against whom such proceeding is contemplated' shall be given notice and a hearing. In the case at bar such notice was addressed only to the corporation. In response thereto the appellant appeared on behalf of the corpora-

<sup>4</sup> See 21 U. S. C. A. S321 (j) and (n).

<sup>5</sup> See *Von Bremen v. United States*, 192 F. 904, 906 (C. C. A. 2), *Weeks v. United States*, 224 F. 64, 68 (C. C. A. 2), and *Strong, Cobb & Co. v. United States*, 103 F. 2d 671, 674 (C. C. A. 6) construing the Food and Drugs Act of 1906. That intention is not necessarily an element of the offense under the existing Act is made very clear by section 303, 21 U. S. C. A. S333 (a) and (b) where different penalties are provided for simple violations and for violations "with intent to defraud or mislead."

<sup>6</sup> 21 U. S. C. A. S335. Hearing before report of criminal violation. Before any violation of this chapter is reported by the Administrator to any United States attorney for institution of a criminal proceeding, the person against whom such proceeding is contemplated shall be given appropriate notice and an opportunity to present his views, either orally or in writing, with regard to such contemplated proceeding.

tion. He contends that a notice addressed to him personally was a condition precedent to his lawful prosecution. The district judge ruled that the provision for notice and a hearing was an administrative direction to the Administrator rather than a jurisdictional requirement for criminal proceedings. We agree with this conclusion. Such was the authoritative construction placed upon a similar provision in the Food and Drugs Act of 1906, 21 U. S. C. A. §11. *United States v. Morgan*, 222 U. S. 274; see also *United States v. King & Howe*, 78 F. 2d 693, 696 (C. C. A. 2). In our opinion the changes in phraseology introduced by the 1938 Act are not such as to render obsolete these decisions. This appears quite clearly from the Congressional debates. 83 Cong. Rec. pp. 7792, 7794, 75th Cong., 3d sess. Articles by certain commentators are cited as expressing the opposite view,<sup>7</sup> but we are constrained to disagree with them.

"The appellant further urges that the jury's failure to convict the corporation is so inconsistent with the finding of guilt on the part of the appellant that the verdict against him cannot stand. Assuming that the statute includes within its prohibitions an agent who acts for his employer in shipping in interstate commerce misbranded or adulterated articles, the contention is without merit. No authority has been cited in support of the argument that failure to convict the principal will avoid the conviction of an agent who has committed all the elements of a crime. We think the usual principle is applicable that error cannot be asserted for inconsistency in the jury's verdict. See *Dunn v. United States*, 284 U. S. 390; *United States v. Pandolfi*, 110 F. 2d 736 (C. C. A. 2).

"A more difficult question is presented by the appellant's contention that the statute is aimed only at punishment of the principal and not at punishment of an innocent agent who in good faith and in ignorance of the misbranding or adulteration takes part in an interstate shipment of food or drugs. Section 301, 21 U. S. C. A. §331, prohibits 'the following acts and the causing thereof,' namely '(a) The introduction or delivery for introduction into interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded.' Section 333 (a) of Title 21 declares that 'any person' who violates any of the provisions of section 331 shall be guilty of a misdemeanor and on conviction be subject to imprisonment or fine or both. The Act defines the term 'person' to include 'individual, partnership, corporation and association.' 21 U. S. C. A. §321 (e). Who is the person causing 'the introduction or delivery for introduction' into interstate commerce of a misbranded drug? Is the clerk who innocently packs or ships it guilty of the offense, as well as the employer for whom he works? While the statutory language seems literally to include all who have any part in causing delivery for introduction into interstate commerce, there are serious objections to so construing it. Subsection (c) of 21 U. S. C. A. §333 provides 'No person shall be subject to the penalties of subsection (a) of this section \* \* \* for having violated section 331 (a) or (d), if he establishes a guaranty or undertaking signed by, and containing the name and address of, the person residing in the United States from whom he received in good faith the article, to the effect, in the case of an alleged violation of section 331 (a), that such article is not adulterated or misbranded within the meaning of this chapter designating this chapter \* \* \*'. Obviously such a guaranty, if given, will be obtained by the drug dealer, not by his clerk who may later deliver the article for shipment in interstate commerce; nor is such clerk literally within the protection of the quoted section, since he is not the one who 'received' the article from the guarantor. It is difficult to believe that Congress expected anyone except the principal to get such a guaranty, or to make the guilt of an agent depend upon whether his employer had gotten one. The agent's guilt, like his principal's, must be independent of any scienter under section 331 (a). It would be extremely harsh to charge him criminally with the risks of the business as the drug dealer is himself charged. A majority of the court is of opinion that this cannot have been the congressional intent and that the statute must be construed to mean that only the drug dealer, whether corporation or individual, is the 'person' who causes the 'introduction' or 'delivery for introduction' of misbranded or adulterated drugs into commerce. In support of this conclusion the appellant adverts to the omission from the present Act of a provision which appeared in the 1906 Act in 21 U. S. C. A. §4. This declared that in construing and enforcing the provisions of sections 1 to 15 of Title 21 'the act, omission, or failure of any officer, agent or other person acting for or employed by any corporation \* \* \* within

<sup>7</sup> See "A Treatise on the Law of Food, Drugs and Cosmetics," 1942, p. 737; Law & Contemporary Problems, published by the School of Law of Duke University, 1939, Vol. 6, p. 74.

the scope of his employment or office, shall in every case be also deemed to be the act, omission or failure of such corporation \* \* \* as well as that of the person.' In our opinion the omission of this provision adds nothing to the argument already developed; it was doubtless omitted as unnecessary because it states an obvious general principle of agency.

"The foregoing discussion has proceeded upon the assumption that if the statute is applicable to the appellant it must also apply to a shipping clerk or any menial employee who was instrumental in causing the forbidden shipment, for we can find no basis in the statutory language for drawing a distinction between agents of high or low rank. We are not, however, to be understood to hold that under no circumstances could an individual conducting a drug business in corporate form be subjected to the penalties of section 331 (a). If an individual operated a corporation as his 'alter ego' or agent he might be the principal; but the evidence hardly went so far as to establish that such was the relationship between the appellant and his corporation and in any event his guilt was not made to turn on any such issue. Accordingly his conviction must be reversed.

"The views above expressed in respect to the construction of the statute are those of a majority of the court. I am not in accord with them. I believe that the language of sections 331 (a) and 333 (a) is so inclusive as to render liable all persons who take part in causing a shipment in interstate commerce of misbranded or adulterated articles, and that any insufficiency in the protection afforded an agent by section 333 (c) is not an adequate reason for limiting the statutory prohibitions to the dealer. The possibility that a literal interpretation of the statute may lead to the prosecution of insignificant agents rather than their employers is not, I believe, a serious risk and is a matter Congress was willing to leave to the good sense of prosecuting officials and trial juries. See *United States v. Buffalo Cold Storage Co.*, 179 F. 865, 867 (D. C. W. D. N. Y.), where a warehouseman who innocently shipped pursuant to instructions was convicted under the 1906 Act; see also the charge given by Judge Grubb in *United States v. Mayfield*, 177 F. 765 (D. C. Ala.).

"Judgment reversed."

On January 3, 1943, a petition for a rehearing was denied by the Circuit Court of Appeals and on February 8, 1943, a petition for a Writ of Certiorari was filed with the United States Supreme Court. Such petition was granted on April 5, 1943, and on November 22, 1943, the Supreme Court rendered the following opinion, which reversed the judgment of the Circuit Court of Appeals:

FRANKFURTER, *Associate Justice*: This was a prosecution begun by two informations, consolidated for trial, charging Buffalo Pharmacal Company, Inc., and Dotterweich, its president and general manager, with violations of the Act of Congress of June, 1938, c. 675, 52 Stat. 1040, 21 U. S. C. §§ 301-392, known as the Federal Food, Drug, and Cosmetic Act. The Company, a jobber in drugs, purchased them from their manufacturers and shipped them, repacked under its own label, in interstate commerce. (No question is raised in this case regarding the implications that may properly arise when, although the manufacturer gives the jobber a guaranty, the latter through his own label makes representations.) The informations were based on § 301 of that Act (21 U. S. C. § 331), paragraph (a) of which prohibits 'The introduction or delivery for introduction into interstate commerce of any . . . drug . . . that is adulterated or misbranded'. 'Any person' violating this provision is, by paragraph (a) of § 303 (21 U. S. C. § 333), made 'guilty of a misdemeanor'. Three counts were to the jury—two, for shipping misbranded drugs in interstate commerce, and a third, for so shipping an adulterated drug. The jury disagreed as to the corporation and found Dotterweich guilty on all three counts. We start with the finding of the Circuit Court of Appeals that the evidence was adequate to support the verdict of adulteration and misbranding. 131 F. 2d 500, 502.

Two other questions which the Circuit Court of Appeals decided against Dotterweich call only for summary disposition to clear the path for the main question before us. He invoked § 305 of the Act requiring the Administrator, before reporting a violation for prosecution by a United States attorney, to give the suspect an 'opportunity to present his views'. We agree with the Circuit Court of Appeals that the giving of such an opportunity, which was not accorded to Dotterweich, is not a prerequisite to prosecution. This Court so held in *United States v. Morgan*, 222 U. S. 274, in construing the Food and Drugs Act of 1906, 34 Stat. 768, and the legislative history to which the court below called attention abundantly proves that Congress, in the changed phraseology of 1938, did not intend to introduce a change of substance. 83 Cong. Rec. 7792-94. Equally base-

less is the claim of Dotterweich that, having failed to find the corporation guilty, the jury could not find him guilty. Whether the jury's verdict was the result of carelessness or compromise or a belief that the responsible individual should suffer the penalty instead of merely increasing, as it were, the cost of running the business of the corporation, is immaterial. Juries may indulge in precisely such motives or vagaries. *Dunn v. United States*, 284 U. S. 390.

"And so we are brought to our real problem. The Circuit Court of Appeals, one judge dissenting, reversed the conviction on the ground that only the corporation was the 'person' subject to prosecution unless, perchance, Buffalo Pharmacal was a counterfeit corporation serving as a screen for Dotterweich. On that issue, after rehearing, it remanded the cause for a new trial. We then brought the case here, on the Government's petition for certiorari, 318 U. S. 753, because this construction raised questions of importance in the enforcement of the Federal Food, Drug, and Cosmetic Act.

"The court below drew its conclusion not from the provisions defining the offenses on which this prosecution was based (§§ 301 (a) and 303 (a)), but from the terms of § 303 (c). That section affords immunity from prosecution if certain conditions are satisfied. The condition relevant to this case is a guaranty from the seller of the innocence of his product. So far as here relevant, the provision for an immunizing guaranty is as follows: 'No person shall be subject to the penalties of subsection (a) of this section . . . (2) for having violated section 301 (a) or (d), if he establishes a guaranty or undertaking signed by, and containing the name and address of, the person residing in the United States from whom he received in good faith the article, to the effect, in case of an alleged violation of section 301 (a), that such article is not adulterated or misbranded, within the meaning of this Act, designating this Act

"The Circuit Court of Appeals found it 'difficult to believe that Congress expected anyone except the principal to get such a guaranty, or to make the guilt of an agent depend upon whether his employer had gotten one.' 131 F. 2d 500, 503. And so it cut down the scope of the penalizing provisions of the Act to the restrictive view, as a matter of language and policy, it took of the 'relieving effect of a guaranty.

"The guaranty clause cannot be read in isolation. The Food and Drugs Act of 1906 was an exertion by Congress of its power to keep impure and adulterated food and drugs out of the channels of commerce. By the Act of 1938, Congress extended the range of its control over illicit and noxious articles and stiffened the penalties for disobedience. The purposes of this legislation thus touch phases of the lives and health of people which, in the circumstances of modern industrialism, are largely beyond self-protection. Regard for these purposes should infuse construction of the legislation if it is to be treated as a working instrument of government and not merely as a collection of English words. See *Hipolite Egg Co. v. United States*, 220 U. S. 45, 57, and *McDermott v. Wisconsin*, 228 U. S. 115, 128. The prosecution to which Dotterweich was subjected is based on a now familiar type of legislation whereby penalties serve as effective means of regulation. Such legislation dispenses with the conventional requirement for criminal conduct—awareness of some wrongdoing. In the interest of the larger good it puts the burden of acting at hazard upon a person otherwise innocent but standing in responsible relation to a public danger. *United States v. Balint*, 258 U. S. 250. And so it is clear that shipments like those now in issue are 'punished by the statute if the article is misbranded [or adulterated], and that the article may be misbranded [or adulterated] without any conscious fraud at all. It was natural enough to throw this risk on shippers with regard to the identity of their wares. . . .' *United States v. Johnson*, 221 U. S. 488, 497-98.

"The statute makes 'any person' who violates § 301(a) guilty of a 'misdemeanor'. It specifically defines 'person' to include 'corporation'. § 201(e). But the only way in which a corporation can act is through the individuals who act on its behalf. *New York Central R. R. v. United States*, 212 U. S. 481. And the historic conception of a 'misdemeanor' makes all those responsible for it equally guilty, *United States v. Mills*, 7 Pet. 138, 141, a doctrine given general application in § 332 of the Penal Code (18 U. S. C. § 550). If, then, Dotterweich is not subject to the Act, it must be solely on the ground that individuals are immune when the 'person' who violates § 301(a) is a corporation, although from the point of view of action the individuals are the corporation. As a matter of

legal development, it has taken time to establish criminal liability also for a corporation and not merely for its agents. See *New York Central R. R. v. United States*, *supra*. The history of federal food and drug legislation is a good illustration of the elaborate phrasing that was in earlier days deemed necessary to fasten criminal liability on corporations. Section 12 of the Food and Drugs Act of 1906 provided that, 'the act, omission, or failure of any officer, agent, or other person acting for or employed by any corporation, company, society, or association, within the scope of his employment or office, shall in every case be, also deemed to be the act, omission, or failure of such corporation, company, society, or association as well as that of the person.' By 1938, legal understanding and practice had rendered such statement of the obvious superfluous. Deletion of words—in the interest of brevity and good draftsmanship<sup>8</sup>—superfluous for holding a corporation criminally liable can hardly be found ground for relieving from such liability the individual agents of the corporation. To hold that the Act of 1938 freed all individuals, except when proprietors, from the culpability under which the earlier legislation had placed them is to defeat the very object of the new Act. Nothing is clearer than that the later legislation was designed to enlarge and stiffen the penal net and not to narrow and loosen it. This purpose was unequivocally avowed by the two committees which reported the bills to the Congress. The House Committee reported that the Act 'seeks to set up effective provisions against abuses of consumer welfare growing out of inadequacies in the Food and Drugs Act of June 30, 1906'. (H. Rep. No. 2139, 75th Cong., 3d Sess., p. 1.) And the Senate Committee explicitly pointed out that the new legislation 'must not weaken the existing laws', but on the contrary 'it must strengthen and extend that law's protection of the consumer.' (S. Rep. No. 152, 75th Cong., 1st Sess., p. 1.) If the 1938 Act were construed as it was below, the penalties of the law could be imposed only in the rare case where the corporation is merely an individual's *alter ego*. Corporations carrying on an illicit trade would be subject only to what the House Committee described as a 'license fee for the conduct of an illegitimate business.'<sup>9</sup> A corporate officer, who even with 'intent to defraud or mislead (§ 303b), introduced adulterated or misbranded drugs into interstate commerce could not be held culpable for conduct which was indubitably outlawed by the 1906 Act. See, e. g., *United States v. Mayfield*, 177 F. 765. This argument proves too much. It is not credible that Congress should by implication have exonerated what is probably a preponderant number of persons involved in acts of disobedience—for the number of non-corporate proprietors is relatively small. Congress, of course, could reverse the process and hold only the corporation and allow its agents to escape. In very exceptional circumstances it may have required this result. See *Sherman v. United States*, 282 U. S. 25. But the history of the present Act, its purposes, its terms, and extended practical construction lead away from such a result once 'we free our minds from the notion that criminal statutes must be construed by some artificial and conventional rule'. *United States v. Union Supply Co.*, 215 U. S. 50, 55.

"The Act is concerned not with the proprietary relation to a misbranded or an adulterated drug but with its distribution. In the case of a corporation such distribution must be accomplished, and may be furthered, by persons standing in various relations to the incorporeal proprietor. If a guaranty immunizes shipments of course it immunizes all involved in the shipment. But simply because if there has been a guaranty it would have been received by the proprietor, whether corporate or individual, as a safeguard for the enterprise, the want of a guaranty does not cut down the scope of responsibility of all who are concerned with transactions forbidden by § 301. To be sure, that casts the risk that there is no guaranty upon all who according to settled doctrines of criminal law are responsible for the commission of a misdemeanor. To read the guaranty section, as did the court below, so as to restrict liability for penalties to the only person who normally would receive a guaranty—the proprietor—disregards the admonition that 'the meaning of a sentence is to be felt rather than to be proved'. *United States v. Johnson*, 221 U. S. 488, 496. It also reads an exception to an important provision safeguarding the public welfare with a

<sup>8</sup> 'The bill has been made shorter and less verbose than previous bills. That has been done without deleting any effective provisions.' S. Rep. No. 152, 75th Cong., 1st Sess., p. 2

<sup>9</sup> In describing the penalty provisions of § 303, the House Committee reported that the Bill 'increases substantially the criminal penalties which some manufacturers have regarded as substantially a license fee for the conduct of an illegitimate business.' H. Rep. No. 2139, 75th Cong., 3d Sess., p. 4.



liberality which more appropriately belongs to enforcement of the central purpose of the Act.

"The Circuit Court of Appeals was evidently tempted to make such a devitalizing use of the guaranty provision through fear that an enforcement of § 301(a) as written might operate too harshly by sweeping within its condemnation any person however remotely entangled in the proscribed shipment. But that is not the way to read legislation. Literalism and evisceration are equally to be avoided. To speak with technical accuracy, under § 301 a corporation may commit an offense and all persons who aid and abet its commission are equally guilty. Whether an accused shares responsibility in the business process resulting in unlawful distribution depends on the evidence produced at the trial and its submission—assuming the evidence warrants it—to the jury under appropriate guidance. The offense is committed, unless the enterprise which they are serving enjoys the immunity of a guaranty, by all who do have such a responsible share in the furtherance of the transaction which the statute outlaws, namely to put into the stream of interstate commerce adulterated or misbranded drugs. Hardship there doubtless may be under a statute which thus penalizes the transaction though consciousness of wrongdoing be totally wanting. Balancing relative hardships, Congress has preferred to place it upon those who have at least the opportunity of informing themselves of the existence of conditions imposed for the protection of consumers before sharing in illicit commerce, rather than to throw the hazard on the innocent public who are wholly helpless.

"It would be too treacherous to define or even to indicate by way of illustration the class of employees which stands in such a responsible relation. To attempt a formula embracing the variety of conduct whereby persons may responsibly contribute in furthering a transaction forbidden by an Act of Congress, to wit, to send illicit goods across state lines, would be mischievous futility. In such matters the good sense of prosecutors, the wise guidance of trial judges, and the ultimate judgment of juries must be trusted. Our system of criminal justice necessarily depends on 'conscience and circumspection in prosecuting officers.' *Nash v. United States*, 229 U. S. 372, 378 even when the consequences are far more drastic than they are under the provision of law before us. See *United States v. Balint, supra* (involving a maximum sentence of five years). For present purpose it suffices to say that in what the defense characterized as 'a very fair charge' the District Court properly left the question of the responsibility of Dotterweich for the shipment to the jury, and there was sufficient evidence to support its verdict."

*Judgment reversed.*

MURPHY, Associate Justice, dissenting: "Our prime concern in this case is whether the criminal sanctions of the Federal Food, Drug, and Cosmetic Act of 1938 plainly and unmistakably apply to the respondent in his capacity as a corporate officer. He is charged with violating § 301(a) of the Act, which prohibits the introduction or delivery for introduction into interstate commerce of any adulterated or misbranded drug. There is no evidence in this case of any personal guilt on the part of the respondent. There is no proof or claim that he ever knew of the introduction into commerce of the adulterated drugs in question, much less that he actively participated in their introduction. Guilt is imputed to the respondent solely on the basis of his authority and responsibility as president and general manager of the corporation.

"It is a fundamental principle of Anglo-Saxon jurisprudence that guilt is personal and that it ought not lightly to be imputed to a citizen who, like the respondent, has no evil intention or consciousness of wrongdoing. It may be proper to charge him with responsibility to the corporation and the stockholders for negligence and mismanagement. But in the absence of clear statutory authorization it is inconsistent with established canons of criminal law to rest liability on an act in which the accused did not participate and of which he had no personal knowledge. Before we place the stigma of a criminal conviction upon any such citizen the legislative mandate must be clear and unambiguous. Accordingly that which Chief Justice Marshall has called 'the tenderness of the law for the rights of individuals'<sup>10</sup> entitles each person, regardless of economic or social status, to an unequivocal warning from the legislature as to whether he is within the class of persons subject to vicarious liability. Congress cannot be deemed to have intended to punish anyone who is not 'plainly and unmistakably'

<sup>10</sup> *United States v. Wiltberger*, 5 Wheat, 76, 95.



within the confines of the statute. *United States v. Lacher*, 134 U. S. 624, 628; *United States v. Gradwell*, 243 U. S. 476, 485.

"Moreover, the fact that individual liability of corporate officers may be consistent with the policy and purpose of a public health and welfare measure does not authorize this Court to impose such liability where Congress has not clearly intended or actually done so. Congress alone has the power to define a crime and to specify the offenders. *United States v. Wiltberger*, 5 Wheat. 76, 95. It is not our function to supply any deficiencies in these respects, no matter how grave the consequences. Statutory policy and purpose are not constitutional substitutes for the requirement that the legislature specify with reasonable certainty those individuals it desires to place under the interdict of the Act. *United States v. Harris*, 177 U. S. 305; *Sarlls v. United States*, 152 U. S. 570.

"Looking at the language actually used in this statute, we find a complete absence of any reference to corporate officers. There is merely a provision in § 303(a) to the effect that 'any person' inadvertently violating § 301(a) shall be guilty of a misdemeanor. Section 201(e) further defines 'person' as including an 'individual, partnership, corporation, and association.'<sup>11</sup> The fact that a corporate officer is both a 'person' and an 'individual' is not indicative of an intent to place vicarious liability on the officer. Such words must be read in light of their statutory environment.<sup>12</sup> Only if Congress has otherwise specified an intent to place corporate officers within the ambit of the Act can they be said to be embraced within the meaning of the words 'person' or 'individual' as here used.

Nor does the clear imposition of liability on corporations reveal the necessary intent to place criminal sanctions on their officers. A corporation is not the necessary and inevitable equivalent of its officers for all purposes.<sup>13</sup> In many respects it is desirable to distinguish the latter from the corporate entity and to impose liability only on the corporation. In this respect it is significant that this Court has never held the imposition of liability on a corporation sufficient, without more, to extend liability to its officers who have no consciousness of wrongdoing.<sup>14</sup> Indeed, in a closely analogous situation, we have held that the vicarious personal liability of receivers in actual charge and control of a corporation could not be predicated on the statutory liability of a 'company,' even when the policy and purpose of the enactment were consistent with personal liability. *United States v. Harris*, *supra*.<sup>15</sup> It follows that express statutory provisions are necessary to

<sup>11</sup> The normal and necessary meaning of such a definition of 'person' is to distinguish between individual enterprises and those enterprises that are incorporated or operated as a partnership or association, in order to subject them to the Act. This phrase cannot be considered as an attempt to distinguish between individual officers of a corporation and the corporate entity. Lee, 'Corporate Criminal Liability,' 28 Col. L. Rev. 1, 181, 190.

<sup>12</sup> Compare *United States v. Cooper Corp.*, 312 U. S. 600, 606, and *Davis v. Pringle*, 268 U. S. 315, 318, holding that the context and legislative history of the particular statutes there involved indicated that the words "any person" did not include the United States. But in *Georgia v. Evans*, 316 U. S. 159, and *Ohio v. Helvering*, 292 U. S. 360, these considerations led to the conclusion that 'any person' did include a state. See also 40 Stat. 1143, which specifically includes officers within the meaning of 'any person' as used in the Revenue Act of 1918.

<sup>13</sup> In *Park Bank v. Remsen*, 158 U. S. 337, 344, this Court said, 'It is the corporation which is given the powers and privileges and made subject to the liabilities. Does this carry with it an imposition of liability upon the trustee or other officer of the corporation? The officer is not the corporation; his liability is personal, and not that of the corporation, nor can it be counted among the powers and privileges of the corporation.'

<sup>14</sup> For an analysis of the confusion on this matter in the state and lower federal courts, see Lee, 'Corporate Criminal Liability,' 28 Col. L. Rev. 1, 181.

<sup>15</sup> In that case we had before us Rev. Stat. §§ 4386-4389, which penalized 'any company, owner or custodian of such animals' who failed to comply with the statutory requirements as to livestock transportation. A railroad company violated the statute and the government sought to impose liability on the receivers who were in actual charge of the company. It was argued that the word 'company' embraced the natural persons acting on behalf of the company and that to hold such officers and receivers liable was within the policy and purpose of so humane a statute. We rejected this contention in language peculiarly appropriate to this case (177 U. S. at 309):

'It must be admitted that, in order to hold the receivers, they must be regarded as included in the word 'company.' Only by a strained and artificial construction, based chiefly upon a consideration of the mischief which the legislature sought to remedy, can receivers be brought within the terms of the law. But can such a kind of construction be resorted to in enforcing a penal statute? Giving all proper force to the contention of counsel of the government, that there has been some relaxation on the part of the courts in applying the rule of strict construction to such statutes, it still remains that the intention of a penal statute must be found in the language actually used, interpreted according to its fair and obvious meaning. It is not permitted to courts, in this class of cases, to attribute inadvertence or oversight to the legislature when enumerating the classes of persons who are subjected to a penal enactment, nor to depart from the settled meaning of words or phrases in order to bring persons not named or distinctly described within the supposed purpose of the statute.'

satisfy the requirement that officers as individuals be given clear and unmistakable warning as to their vicarious personal liability. This Act gives no such warning.

"This fatal hiatus in the Act is further emphasized by the ability of Congress, demonstrated on many occasions, to apply statutes in no uncertain terms to corporate officers as distinct from corporations.<sup>16</sup> The failure to mention officers specifically is thus some indication of a desire to exempt them from liability. In fact the history of federal food and drug legislation is itself illustrative of this capacity for specification and lends strong support to the conclusion that Congress did not intend to impose liability on corporate officers in this particular Act.

"Section 2 of the Federal Food and Drugs Act of 1906, as introduced and passed in the Senate, contained a provision to the effect that any violation of the Act by a corporation should be deemed to be the act of the officer responsible therefor and that such officer might be punished as though it were his personal act.<sup>17</sup> This clear imposition of criminal responsibility on corporate officers, however, was not carried over into the statute as finally enacted. In its place appeared merely the provision that 'when construing and enforcing the provisions of this Act, the act, omission, or failure of any officer, agent, or other person acting for or employed by any corporation . . . within the scope of his employment or office, shall in every case be also deemed to be the act, omission, or failure of such corporation . . . as well as that of the person.'<sup>18</sup> This provision had the effect only of making corporations responsible for the illegal acts of their officers and proved unnecessary in view of the clarity of the law to that effect. *New York Central & H. R. Co. v. United States*, 212 U. S. 481.

"The framers of the 1938 Act were aware that the 1906 Act was deficient in that it failed 'to place responsibility properly upon corporate officers.'<sup>19</sup> In order 'to provide the additional scope necessary to prevent the use of the corporate form as a shield to individual wrongdoers,'<sup>20</sup> these framers inserted a clear provision that 'whenever a corporation or association violates any of the provisions of this Act, such violation shall also be deemed to be a violation of the individual directors, officers, or agents of such corporation or association who authorized, ordered, or did any of the acts constituting, in whole or in part, such violation.'<sup>21</sup> This paragraph, however, was deleted from the final version of the Act.

<sup>16</sup> "Whenever a corporation shall violate any of the penal provisions of the antitrust laws, such violation shall be deemed to be also that of the individual directors, officers, or agents of such corporation who shall have authorized, ordered, or done any of the acts constituting in whole or in part such violation." 15 U. S. C. § 24.

"The courts of bankruptcy . . . are invested . . . with such jurisdiction at law and in equity as will enable them to . . . (4) arraign, try, and punish bankrupts, officers, and other persons, and the agents, officers, members of the board of directors or trustees, or other similar controlling bodies, of corporations for violations of the provisions contained in this title." 11 U. S. C. § 11.

"Any such common carrier, or any officer or agent thereof, requiring or permitting any employee to go, be, or remain on duty in violation of the next preceding section of this chapter shall be liable to a penalty . . ." 45 U. S. C. § 63.

"A mortgagor who, with intent to defraud, violates any provision of subsection F, section 924, and if the mortgagor is a corporation or association, the president or other principal executive officer of the corporation or association, shall upon conviction thereof be held guilty of a misdemeanor . . ." 46 U. S. C. § 941 (b).

<sup>17</sup> S. 88, 59th Cong., 1st Sess. Senator Heyburn, one of the sponsors of S. 88, stated that this was "a new feature in bills of this kind. It was intended to obviate the possibility of escape by officers of a corporation under a plea, which has been more than once made, that they did not know that this was being done on the credit of or on the responsibility of the corporation." 40 Cong. Rec. 894.

<sup>18</sup> 34 Stat. 772, 21 U. S. C. § 4.

<sup>19</sup> Senate Report No. 493, 73d Cong., 2d Sess., p. 21.

<sup>20</sup> *Ibid.*, p. 22. This report also stated that "it is not, however, the purpose of this paragraph to subject to liability those directors, officers, and employees, who merely authorize their subordinates to perform lawful duties and such subordinates, on their own initiative, perform those duties in a manner which violates the provisions of the law. However, if a director or officer personally orders his subordinate to do an act in violation of the law, there is no reason why he should be shielded from personal responsibility merely because the act was done by another and on behalf of a corporation."

<sup>21</sup> This provision appears in several of the early versions of the Act introduced in Congress. S. 1944, 73d Cong., 1st Sess., § 18(b); S. 2000, 73d Cong., 2d Sess., § 18(b); S. 2800, 73d Cong., 2d Sess., § 18(b); S. 5, 74th Cong., 1st Sess., § 709(b); S. 5, 74th Cong., 2d Sess., § 707(b), as reported to the House, which substituted the word "personally" for the word "authorized" in the last clause of the paragraph quoted above. A variation of this provision appeared in S. 5, 75th Cong., 1st Sess., § 2(f), and made a marked distinction between the use of the word "person" and the words "director, officer, employee, or agent acting for or employed by any person." All of these bills also contained the present definition of "person" as including "individual, partnership, corporation, and association."

"We cannot presume that this omission was inadvertent on the part of Congress. *United States v. Harris, supra* at 309. Even if it were, courts have no power to remedy so serious a defect, no matter how probable it otherwise may appear that Congress intended to include officers; 'probability is not a guide which a court, in construing a penal statute, can safely take.' *United States v. Wiltberger, supra* at 105. But the framers of the 1938 Act had an intelligent comprehension of the inadequacies of the 1906 Act and, of the unsettled state of the law. They recognized the necessity of inserting clear and unmistakable language in order to impose liability on corporate officers. It is thus unreasonable to assume that the omission of such language was due to a belief that the Act as it now stands was sufficient to impose liability on corporate officers. Such deliberate deletion is consistent only with an intent to allow such officers to remain free from criminal liability. Thus to apply the sanctions of this Act to the respondent would be contrary to the intent of Congress as expressed in the statutory language and in the legislative history.

"The dangers inherent in any attempt to create liability without express Congressional intention or authorization are illustrated by this case. Without any legislative guides, we are confronted with the problem of determining precisely which officers, employees and agents of a corporation are to be subject to this Act by our fiat. To erect standards of responsibility is a difficult legislative task and the opinion of this Court admits that it is 'too treacherous' and a 'mischievous futility' for us to engage in such pursuits. But the only alternative is a blind resort to 'the good sense of prosecutors, the wise guidance of trial judges, and the ultimate judgment of juries.' Yet that situation is precisely what our constitutional system sought to avoid. Reliance on the legislature to define crimes and criminals distinguishes our form of jurisprudence from certain less desirable ones. The legislative power to restrain the liberty and to imperil the good reputation of citizens must not rest upon the variable attitudes and opinions of those charged with the duties of interpreting and enforcing the mandates of the law. I therefore cannot approve the decision of the Court in this case.

"Mr. Justice ROBERTS, Mr. Justice REED and Mr. Justice RUTLEDGE join in this dissent."

**918. Adulteration and misbranding of elixir phenobarbital. U. S. v. The Lieben-thal Brothers Co. (Marlo Products Co.). Plea of guilty. Fine, \$500 and costs. (F. D. C. No. 7274. Sample No. 71157-E.)**

This product was sold under a name recognized in the National Formulary, an official compendium, and differed in strength and quality from the standard prescribed in such authority.

On August 21, 1942, the United States attorney for the Northern District of Ohio filed an information against the Lieben-thal Brothers Co., a corporation, trading under the name of Marlo Products Co., Cleveland, Ohio, alleging shipment on or about December 18, 1941, from the State of Ohio into the State of Missouri of a quantity of elixir phenobarbital which was adulterated and misbranded.

The article was alleged to be adulterated in that it purported to be and was represented as a drug, the name of which, elixir of phenobarbital, is recognized in the National Formulary, an official compendium, and its strength differed from and its quality fell below the standard set forth therein since it contained not more than 0.107 gram of phenobarbital in each 100 cc., whereas the Formulary provides that elixir of phenobarbital shall contain not less than 0.37 gram of phenobarbital in each 100 cc.; and its difference in strength and quality from the standard set forth in the compendium was not plainly stated on its label.

It was alleged to be misbranded in that the statement, "Elixir Phenobarbital N. F. \* \* \* Each fluid ounce contains 1.83 grains Phenobarbital," borne on its label, was false and misleading since the statement represented that the article consisted of elixir of phenobarbital which complied with the requirements of the National Formulary and that each fluid ounce thereof contained 1.83 grains of phenobarbital, whereas the article did not consist of elixir of phenobarbital which complied with such requirements, and each fluid ounce thereof contained not more than 0.49 grain of phenobarbital.

On April 13, 1943, the defendant having entered a plea of guilty, the court imposed a fine of \$500 and costs.